

1614

X

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Grant

Serial No.: 09/804,484

Filed: 3/13/2001

Group Art Unit: 1614

PHC
RECEIVED

AUG 05 2002

TECH CENTER 1600/2900

Title: Compositions for Treating
Retinopathy and Methods of Using
Same

Attorney Docket No.: UF-10287R

Assistant Commissioner for Patents
Washington, D.C. 20231



INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This Information Disclosure Statement is submitted:

- ☒ under 37 CFR 1.97(b), or
(Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
- ☐ under 37 CFR 1.97(c) together with either a:
- ☐ Certification under 37 CFR 1.97(e), or
 - ☐ a \$240.00 fee under 37 CFR 1.17(p), or
- (After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with a:
- ☐ Certification under 37 CFR 1.97(e), and
 - ☐ a petition under 37 CFR 1.97(d)(2)(ii), and
 - ☐ a \$130.00 petition fee set forth in 37 CFR 1.17(i)(1).
- (Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

☒ Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

2

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

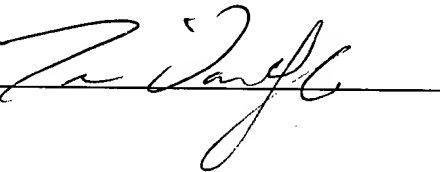
Respectfully submitted,

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope with sufficient postage addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit: 7-23-2002

Typed Name: Timothy H. Van Dyke

Signature:



Timothy H. Van Dyke
Attorney/Agent for Applicant(s)
Reg. No. 43218

Date: 7-23-2002

Customer No: 29847

Van Dyke & Associates, P.A.
1630 Hillcrest Street
Orlando, FL 32803
Phone: 407-228-0328; Fax: 407-228-0329

PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

RECEIVED

[illegible]

Examiner Signature	Jeffrey E. Russell	Date Considered	September 17, 2002
-----------------------	--------------------	--------------------	--------------------

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +

Approved for use through 10/31/99. OMB 0651-0031
 Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
 Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	09/804.484	
			Filing Date	3/13/2001	
			First Named Inventor	Grant	
			Group Art Unit	1614 1653	
			Examiner Name	Unknown	
Sheet	2	of	4	Attorney Docket Number	UF-10287R

RECEIVED

AUG 05 2002

TECH CENTER 600/2900

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JR		ANONYMOUS, <i>MMWR</i> (1993) 42(10): 191-195.	
JR		PLEWE, G. <i>et al.</i> "Somatostatin analogue SMS 201-995 in type I diabetes mellitus. Initial experience after repeated administration." <i>Scand J Gastroenterol Suppl.</i> (1986) 119: 166-169.	
JR		KLEIN, <i>et al.</i> <i>Ophthalmol.</i> (1984) 91: 10-17.	
JR		MERIMEE, T.J. <i>New England Journal of Medicine.</i> (1990) 322: 978-983.	
JR		MURPHY, <i>American Family Physician</i> (1995) 51(4): 785-796.	
JR		ROHRER, <i>et al.</i> "Rapid identification of subtype-selective agonists of the somatostatin receptor through combinatorial chemistry" <i>Science.</i> (1998) 282: 737-740.	
JR		PATEL and SRIKANT, <i>Endocrinology.</i> (1994) 135(6): 2814-7.	
JR		VALLI, <i>et al.</i> <i>Ophthalmologica.</i> (1995) 209(13): 117-121.	
JR		ASHP <i>Handbook on Injectable Drugs.</i> Trissel, 4 th ed. (1986) 622-630.	
JR		AIELLO, <i>et al.</i> <i>PNAS USA.</i> (1995) 92: 10457-10461.	
JR		DHAR, <i>et al.</i> <i>Mol. Pharmacol.</i> (1990) 37: 519-525.	



Examiner Signature	Jeffrey E. Russel	Date Considered	September 17, 2002
--------------------	-------------------	-----------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this box → +

PTO/SB/08B (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

RECEIVED

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	09/804.484
				Filing Date	3/13/2001
				First Named Inventor	Grant
				Group Art Unit	1614
				Examiner Name	Unknown
Sheet	3	of	4	Attorney Docket Number	UF-10287R

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JRN		ASAHI, <i>et al.</i> <i>FEBS Letter.</i> (1992) 309: 10-14.	
JRN		TOMLINSON, <i>et al.</i> <i>Pharmac. Ther.</i> (1992) 54: 151-194.	
JRN		THE DIABETIC RETINOPATHY STUDY RESEARCH GROUP "Indications for photocoagulation treatment of diabetic retinopathy: Diabetic Retinopathy Study Report No: 14" <i>Int. Ophthalmol. Clin.</i> (1987) 27: 239.	
JRN		EARLY TREATMENT DIABETIC RETINOPATHY STUDY RESEARCH GROUP "Techniques for scatter and local photocoagulation treatment of diabetic retinopathy. Early Treatment Diabetic Research Study Report No. 3" <i>Int. Ophthalmol. Clin.</i> (1987) 27: 254-264.	
JRN		KIRKEGAARD, <i>et al.</i> "Effect of one year continuous subcutaneous infusion of a somatostatin analogue, octreotide, on early retinopathy, metabolic control and thyroid function in Type-1 (insulin-dependent) diabetes mellitus" <i>Acta Endocrinol (Copenh)</i> (1990) 122: 766-72.	
JRN		COLAS, <i>et al.</i> "Stimulation of a membrane tyrosine phosphatase activity by somatostatin analogues in rat pancreatic acinar cells" <i>Eur. J. Biochem.</i> (1992) 207: 1017-1024.	
JRN		LESZCZYNSKI, <i>et al.</i> "Rat heart smooth muscle cells express high and low affinity receptors for somatostatin-14, which are involved in regulation of cell proliferation" <i>Life Sci.</i> (1993) 53: 1663-1674.	
JRN		GRANT, <i>et al.</i> "Inhibition of IGF-I and b-FGF stimulated growth of human retinal endothelial cells by the somatostatin analogue, octreotide: a potential treatment for ocular neovascularization" <i>Regul Pept</i> (1993) 48: 267-278.	
JRN		GRANT, <i>et al.</i> <i>Diabetes.</i> (1986) 35: 416-420.	
JRN		MEYER-SCHWICKERATH, <i>et al.</i> <i>J. Clin. Invest.</i> (1993) 92: 2620-2625.	
JRN		GRANT, <i>et al.</i> <i>Ann Ny Acad Science.</i> (1993) 692: 230-242.	

Examiner Signature	Jeffrey E. Russell	Date Considered	September 17, 2002
--------------------	--------------------	-----------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this box → +

PTO/SB/08B (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	09/804.484
				Filing Date	3/13/2001
				First Named Inventor	Grant
				Group Art Unit	1614/653
				Examiner Name	Unknown
Sheet	4	of	4	Attorney Docket Number	UF-10287R

RECEIVED
AUG 05 2002
TECH CENTER 1600/2900

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JR		DANIS, et al. <i>Ophthalmology</i> . (1997) 104: 1661-1669.	
JR		AMIEL, et al. <i>Diabetes</i> . (1984) 33: 1175-1179.	
JR		TAN, et al. <i>J. Clin. Endocrinol. Metab.</i> (1986) 63: 651-655.	
JR		KOLACZYNSKI, et al. <i>Ann Intern Med.</i> (1994) 120: 47-55.	
JR		LANGFORD, et al. <i>Eur. J. Clin. Invest.</i> (1993) 23: 503-516.	
JR		KOLLER, et al. <i>J. Clin Endocrinol Metab.</i> (1998) 83: 2380-2383.	
JR		AIELLO, et al. <i>Diabetes</i> . (1997) 46: 1473-1480.	
JR		SMITH, et al. <i>Science</i> . (1997) 276: 1706-1709.	
JR		McCOMBE, M. et al. "Effect of long-acting somatostatin analogue (BIM23014) on proliferative diabetic retinopathy: a pilot study" <i>Eye</i> (1991) 5: 569-575.	
		GRANT, MARIA, et al. "Ocreotide Retards Progression of Diabetic Retinopathy in Patients Treated with Thyroxine" University of Florida, College of Medicine.	

Examiner Signature	Jeffrey E. Russel	Date Considered	September 17, 2002
--------------------	-------------------	-----------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Notice of References CitedApplication/Control No.
09/804,484Applicant(s)/Patent Under
Reexamination
GRANT, MARIAExaminer
Jeffrey E. RusselArt Unit
1653

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,440,933-B1	08-2002	Bodor et al	514/11
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Grant et al. Octreotide Retards Progression of Diabetic Retinopathy in Patients Treated with Thyroid Hormone. Diabetes. 1999, Vol. 48, Suppl. 1, pages A155-A156, Abstract No. 0674.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

JER
9-18-2002